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Attorneys for Plaintiff Hemopet

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

HEMOPET, Plaintiff, vs. HILL'S PET NUTRITION, INC., Defendant.	Case No. SACV 12-01908-(JST-JPRx) **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** JURY TRIAL DEMANDED

Plaintiff Hemopet files this First Amended Complaint for patent infringement against Defendant Hill's Pet Nutrition Inc. ("Defendant"). Plaintiff Hemopet alleges:

THE PARTIES

1. Hemopet is a 501(c)(3) organization duly organized and existing under the laws of California with its principal place of business in Garden Grove, California.

2. Hemopet is the assignee and owner of four patents at issue in this action, U.S. Patent Nos. 7,865,343, 8,060,354, 8,224,587 and 8,234,099.

3. Hemopet is informed and believes, and on that basis alleges, that Hill's Pet Nutrition Inc. ("Hill's") is a Delaware corporation with its principal place of business at 400 SW 8th Ave., Topeka, KS 66603-3925.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*

5. Venue is proper in this federal district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b) because plaintiff Hemopet is a 501(c)(3) organization located in Orange County, California, with its principal place of business in Garden Grove, California.

6. Defendant has done business in this District, has sold products made with infringing systems and methods in this District, and continues to sell products made with infringing methods in this District, entitling Hemopet to relief.

INFRINGEMENT OF U.S. PATENT NO. 7,865,343

7. On January 4, 2011, United States Patent No. 7,865,343 (the "'343 patent") was duly and legally issued for an invention entitled "Method of Analyzing Nutrition for a Canine or Feline Animal." Hemopet was assigned the '343 patent and continues to hold all rights and interest in the '343 patent. A true and correct copy of the '343 patent is attached hereto as Exhibit A.

8. Hill's has infringed and continues to infringe the '343 patent by its manufacture, use, sale, importation, and/or offer for sale of its products and services

utilizing Hill's Active Ingredient Identification Method (AIM) process and Hill's Prescription Diet r/d and j/d products. Hill's is liable for its infringement of the '343 patent pursuant to 35 U.S.C. § 271.

9. Defendant Hill's acts of infringement have caused damage to Hemopet, and Hemopet is entitled to recover from Hill's the damages sustained by Hemopet as a result of Defendant's wrongful acts in an amount subject to proof at trial. Defendant's infringement of Hemopet's exclusive rights under the '343 patent will continue to damage Hemopet, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by this Court.

INFRINGEMENT OF U.S. PATENT NO. 8,060,354

10. On November 15, 2011, United States Patent No. 8,060,354 (the "'354 patent") was duly and legally issued for an invention entitled "System and Method for Determining a Nutritional Diet for a Canine or Feline Animal." Hemopet was assigned the '354 patent and continues to hold all rights and interest in the '354 patent. A true and correct copy of the '354 patent is attached hereto as Exhibit B.

11. Hill's has infringed and continues to infringe the '354 patent by its manufacture, use, sale, importation, and/or offer for sale of its products and services utilizing Hill's Active Ingredient Identification Method (AIM) process and Hill's Prescription Diet r/d and j/d products. Hill's is liable for its infringement of the '354 patent pursuant to 35 U.S.C. § 271.

12. Defendant's acts of infringement have caused damage to Hemopet, and Hemopet is entitled to recover from Defendant the damages sustained by Hemopet as a result of Defendant's wrongful acts in an amount subject to proof at trial. Defendant's infringement of Hemopet's exclusive rights under the '354 patent will continue to damage Hemopet, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by this Court.

INFRINGEMENT OF U.S. PATENT NO. 8,224,587

13. On July 17, 2012, United States Patent No. 8,224,587 (the "'587 patent") was duly and legally issued for an invention entitled "Method and System for Determining a Nutritional Diet for a Canine or Feline Animal." Hemopet was assigned the '587 patent and continues to hold all rights and interest in the '587 patent. A true and correct copy of the '587 patent is attached hereto as Exhibit C.

14. Hill's has infringed and continues to infringe the '587 patent by its manufacture, use, sale, importation, and/or offer for sale of its products and services utilizing Hill's Active Ingredient Identification Method (AIM) process and Hill's Prescription Diet r/d and j/d products. Hill's is liable for its infringement of the '587 patent pursuant to 35 U.S.C. § 271.

15. Defendant's acts of infringement have caused damage to Hemopet, and Hemopet is entitled to recover from Defendant the damages sustained by Hemopet as a result of Defendant's wrongful acts in an amount subject to proof at trial. Defendant's infringement of Hemopet's exclusive rights under the '587 patent will continue to damage Hemopet, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by this Court.

INFRINGEMENT OF U.S. PATENT NO. 8,234,099

16. On July 31, 2012, United States Patent No. 8,234,099 (the "'099 patent") was duly and legally issued for an invention entitled "Computer Program for Determining a Nutritional Diet Product for a Canine or Feline Animal." Hemopet was assigned the '099 patent and continues to hold all rights and interest in the '099 patent. A true and correct copy of the '099 patent is attached hereto as Exhibit D.

17. Hill's has infringed and continues to infringe the '099 patent by its manufacture, use, sale, importation, and/or offer for sale of its products and services utilizing Hill's Active Ingredient Identification Method (AIM) process and Hill's

Prescription Diet r/d and j/d products. Hill's is liable for its infringement of the '099 patent pursuant to 35 U.S.C. § 271.

18. Defendant's acts of infringement have caused damage to Hemopet, and Hemopet is entitled to recover from Defendant the damages sustained by Hemopet as a result of Defendant's wrongful acts in an amount subject to proof at trial. Defendant's infringement of Hemopet's exclusive rights under the '099 patent will continue to damage Hemopet, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by this Court.

WILLFUL INFRINGEMENT

19. Upon information and belief, the Defendant's infringement of any or all of the above-named patents is willful and deliberate, entitling Hemopet to increased damages under 35 U.S.C. § 284 and to attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

20. Hill's had prior knowledge of the patented technology because it was cited in one of Hill's own patent applications. Hill's cited the parent patents, U.S. Patent Nos. 6,730,023, and 6,287,254, to the patents in suit to the Examiner during the prosecution of Patent Application No. 11/469,565. In addition, Hemopet provided notice of at least two of the patents, U.S. Patents 7,865,343 and 8,060,354, to Hill's and/or Hill's corporate parent.

JURY DEMAND

21. Hemopet demands a trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Hemopet requests entry of judgment in its favor and against Defendant Hill's as follows:

a) Declaration that Hill's has infringed directly, and/or indirectly, U.S. Patent Nos. 7,865,343, 8,060,354, 8,224,587, and 8,234,099;

b) Permanently enjoining Hill's and their respective officers, agents, employees, and those acting in privity with them, from further infringement,

contributory infringement and/or inducing infringement of U.S. Patent Nos. 7,865,343, 8,060,354, 8,224,587, and 8,234,099;

c) Awarding the damages arising out of Hill's infringement of U.S. Patent Nos. 7,865,343, 8,060,354, 8,224,587, and 8,234,099, including enhanced damages pursuant to 35 U.S.C. § 284 together with prejudgment and post-judgment interest, in an amount according to proof;

d) An award of attorney's fees pursuant to 35 U.S.C. § 285 or as otherwise permitted by law; and

e) For such other costs and further relief as the Court may deem just and proper.

Dated: January 16, 2013

MARC M. SELTZER
DAVID H. OROZCO
JOSEPH S. GRINSTEIN
SUSMAN GODFREY L.L.P.

By: _____
David H. Orozco
Attorneys for Plaintiff Hemopet

EXHIBIT A

EXHIBIT A

US007865343B2

(12) **United States Patent**
Dodds

(10) **Patent No.: US 7,865,343 B2**
(45) **Date of Patent: *Jan. 4, 2011**

(54) **METHOD OF ANALYZING NUTRITION FOR A CANINE OR FELINE ANIMAL**

(76) Inventor: **W. Jean Dodds**, 938 Stanford St., Santa Monica, CA (US) 90403

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/355,721**

(22) Filed: **Jan. 16, 2009**

(65) **Prior Publication Data**

US 2009/0132465 A1 May 21, 2009

Related U.S. Application Data

(60) Division of application No. 10/635,707, filed on Aug. 5, 2003, now Pat. No. 7,548,839, which is a continuation-in-part of application No. 09/419,192, filed on Oct. 15, 1999, now Pat. No. 6,730,023, and a continuation-in-part of application No. 09/432,851, filed on Nov. 2, 1999, now Pat. No. 6,287,254.

(60) Provisional application No. 60/403,203, filed on Aug. 12, 2002.

(51) **Int. Cl.**
G06G 7/48 (2006.01)
G01N 33/48 (2006.01)

(52) **U.S. Cl.** **703/11**; 702/19

(58) **Field of Classification Search** ..... None
See application file for complete search history.

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(Continued)

Primary Examiner—Marjorie Moran
Assistant Examiner—Pablo Whaley

(57) **ABSTRACT**

Selecting the nutrition for an animal or animal group comprises performing a diagnostic test to obtain first data. A data base that comprises first data relating a genomic analysis of a bodily fluid or tissue sample from an animal to a physiological condition and optionally the genotype of the animal is accessed. A data base that comprises second data relating to effects of nutrition on genomic analysis is accessed. The first and second data are processed with input data defining the physiological condition and optionally the genotype of the animal or animal group to derive the nutrition for an animal or animal group.

13 Claims, 18 Drawing Sheets

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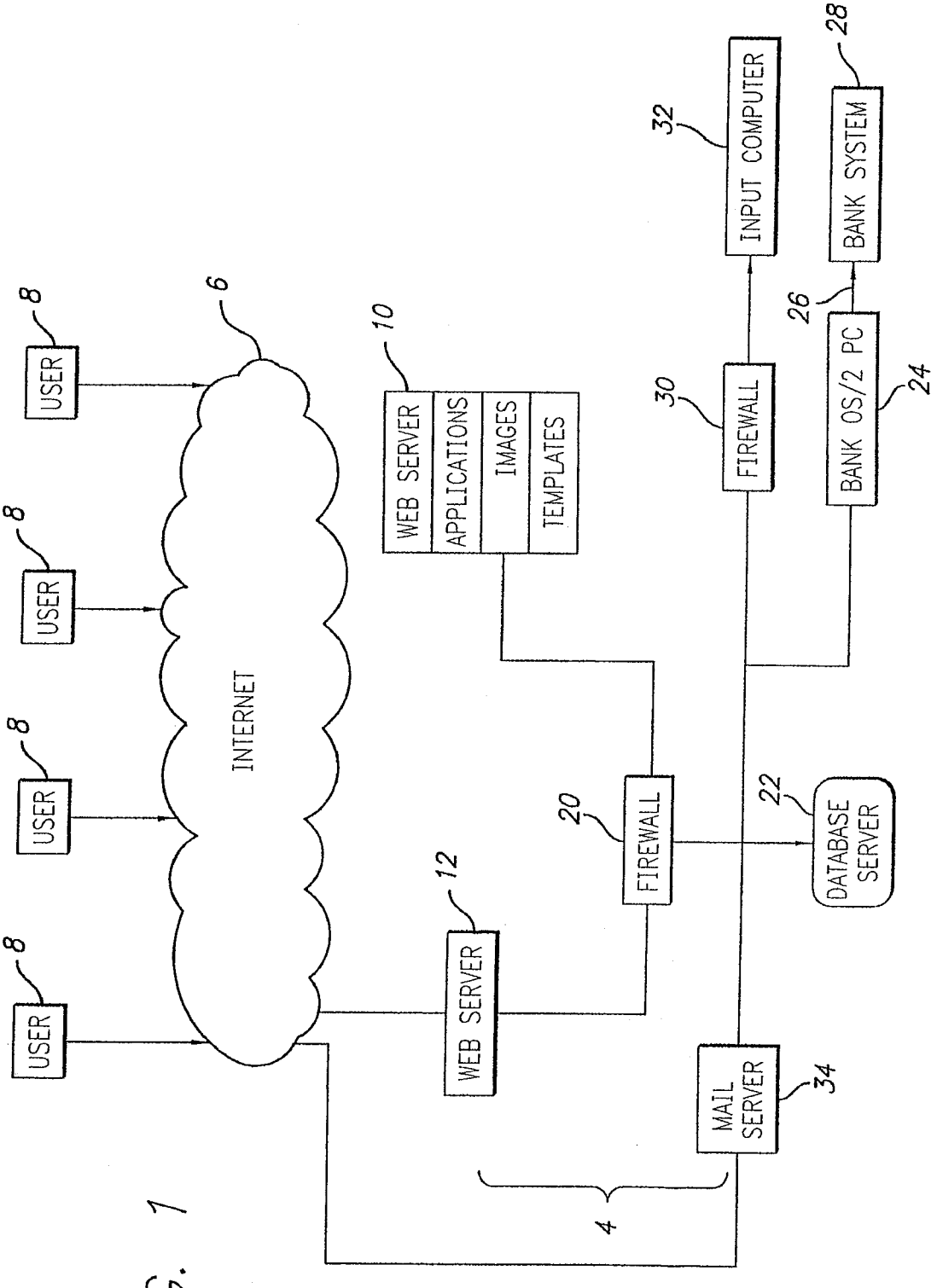
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8
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INTERNET
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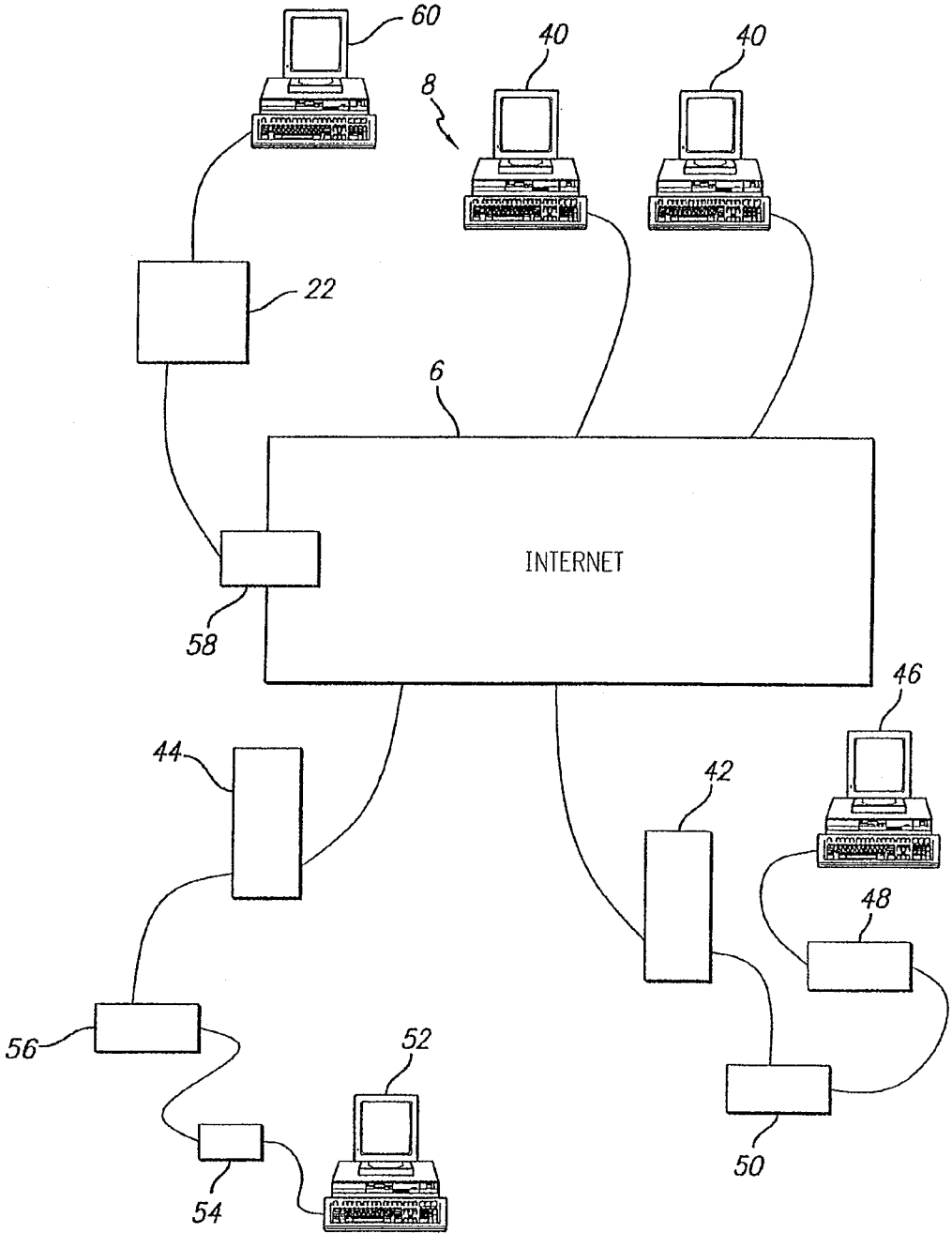
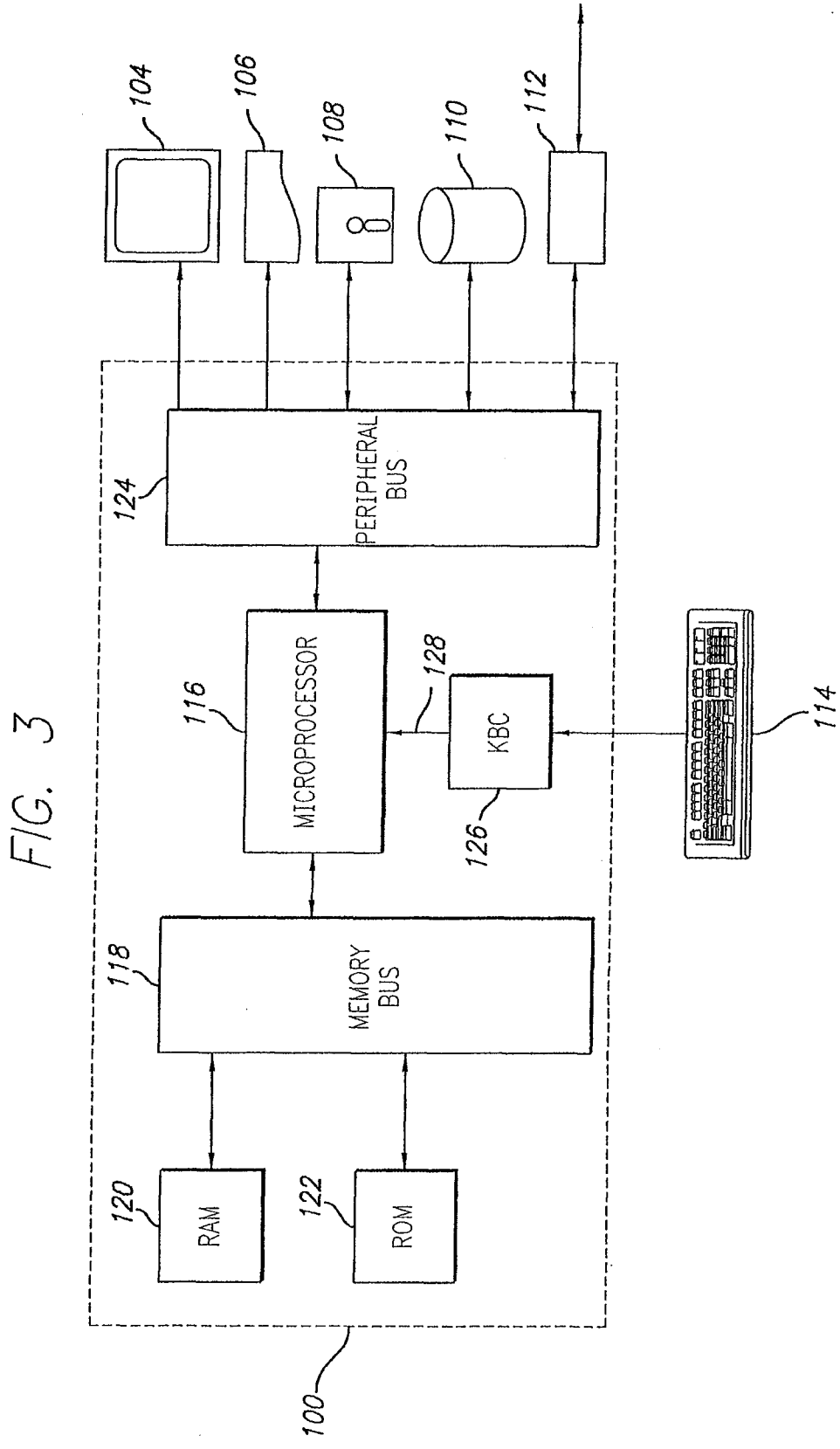
WEB SERVER
APPLICATIONS
IMAGES
TEMPLATES
12
WEB SERVER
20
FIREWALL
22
DATABASE SERVER
30
FIREWALL
32
INPUT COMPUTER
28
BANK SYSTEM
26
BANK OS/2 PC
24
MAIL SERVER
34
4

FIG. 1

FIG. 2

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KBC
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MEMORY BUS
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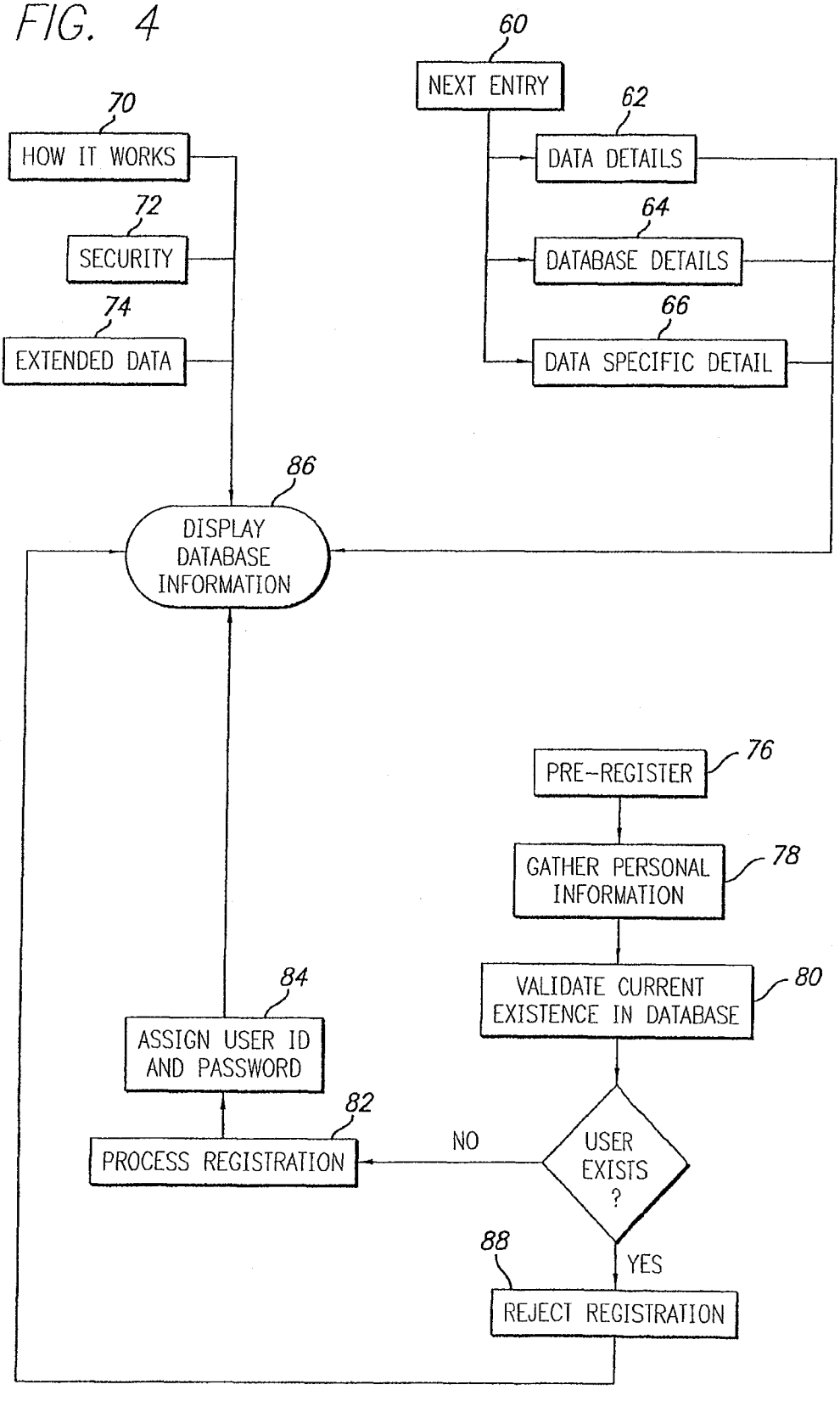
RAM
120
ROM
122
100

FIG. 3

FIG. 4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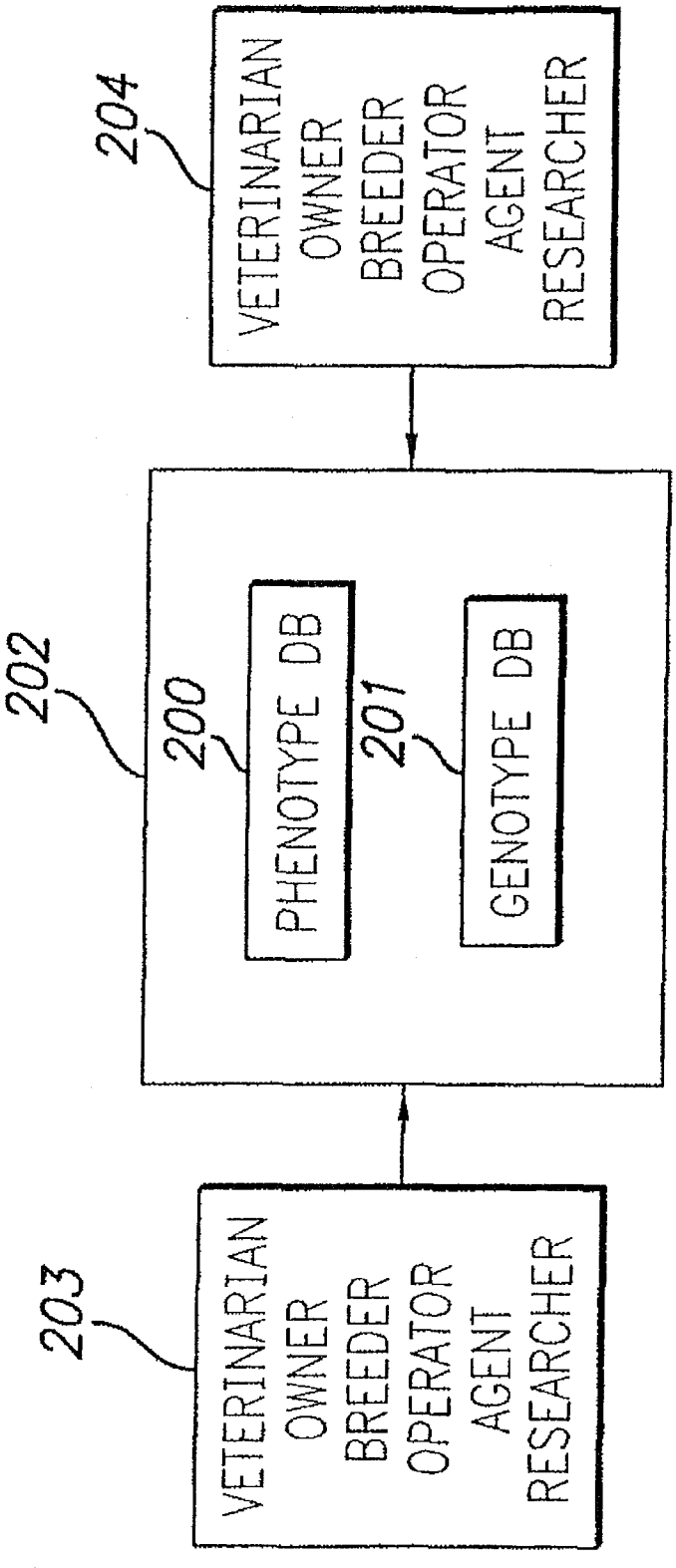
DATA DETAILS
64
DATABASE DETAILS
66
DATA SPECIFIC DETAIL
70
HOW IT WORKS
72
SECURITY
74
EXTENDED DATA
86
DISPLAY DATABASE INFORMATION
76
PRE-REGISTER
78
GATHER PERSONAL INFORMATION
80
VALIDATE CURRENT EXISTENCE IN DATABASE
USER EXISTS ?
NO
YES
82
PROCESS REGISTRATION
84
ASSIGN USER ID AND PASSWORD
88
REJECT REGISTRATION

FIG. 5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BREEDER
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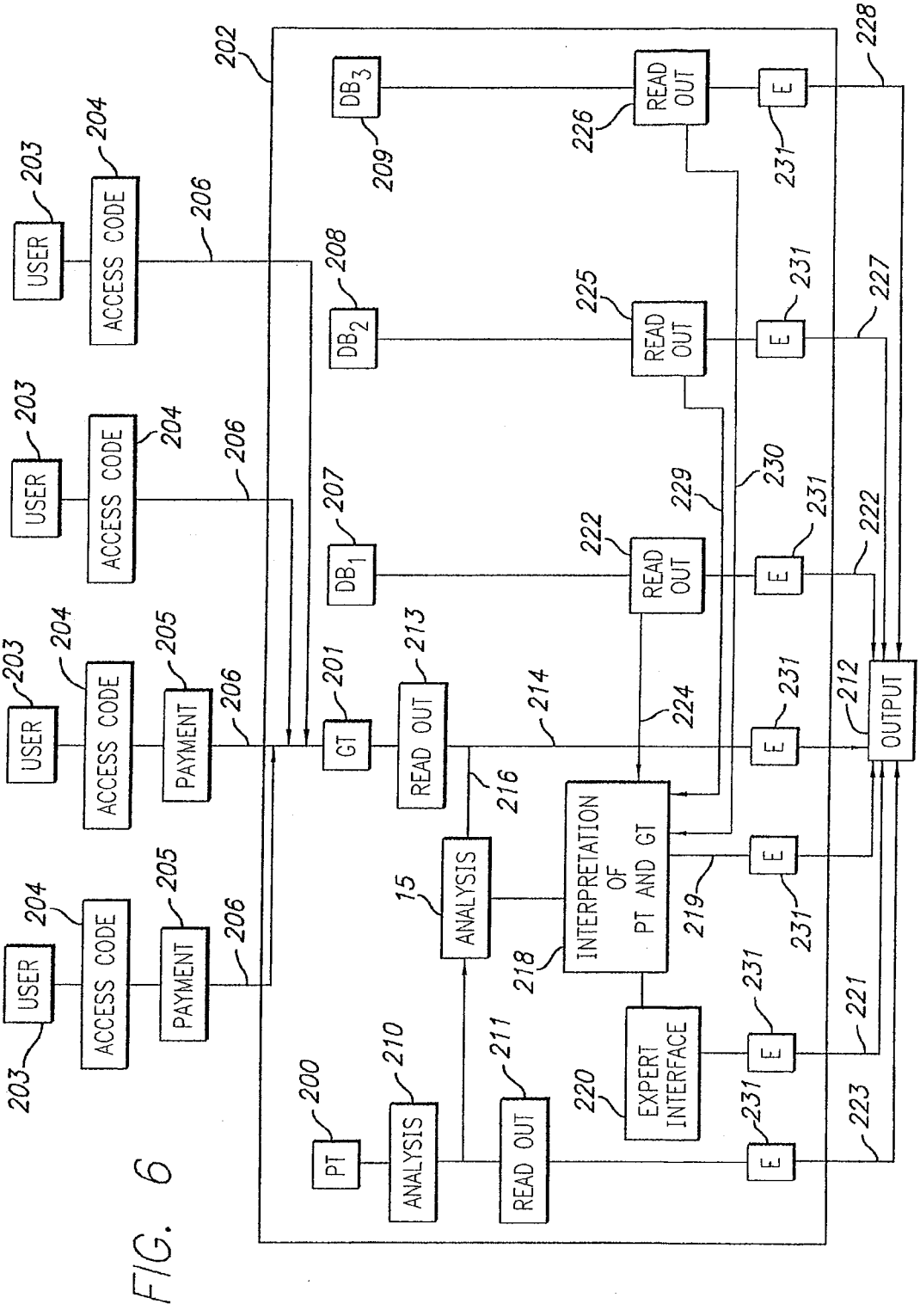
RESEARCHER


USER
ACCESS CODE
PAYMENT
GT
READ OUT
ANALYSIS
INTERPRETATION OF PT AND GT
EXPERT INTERFACE
PT
DB1
DB2
DB3
E
OUTPUT
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
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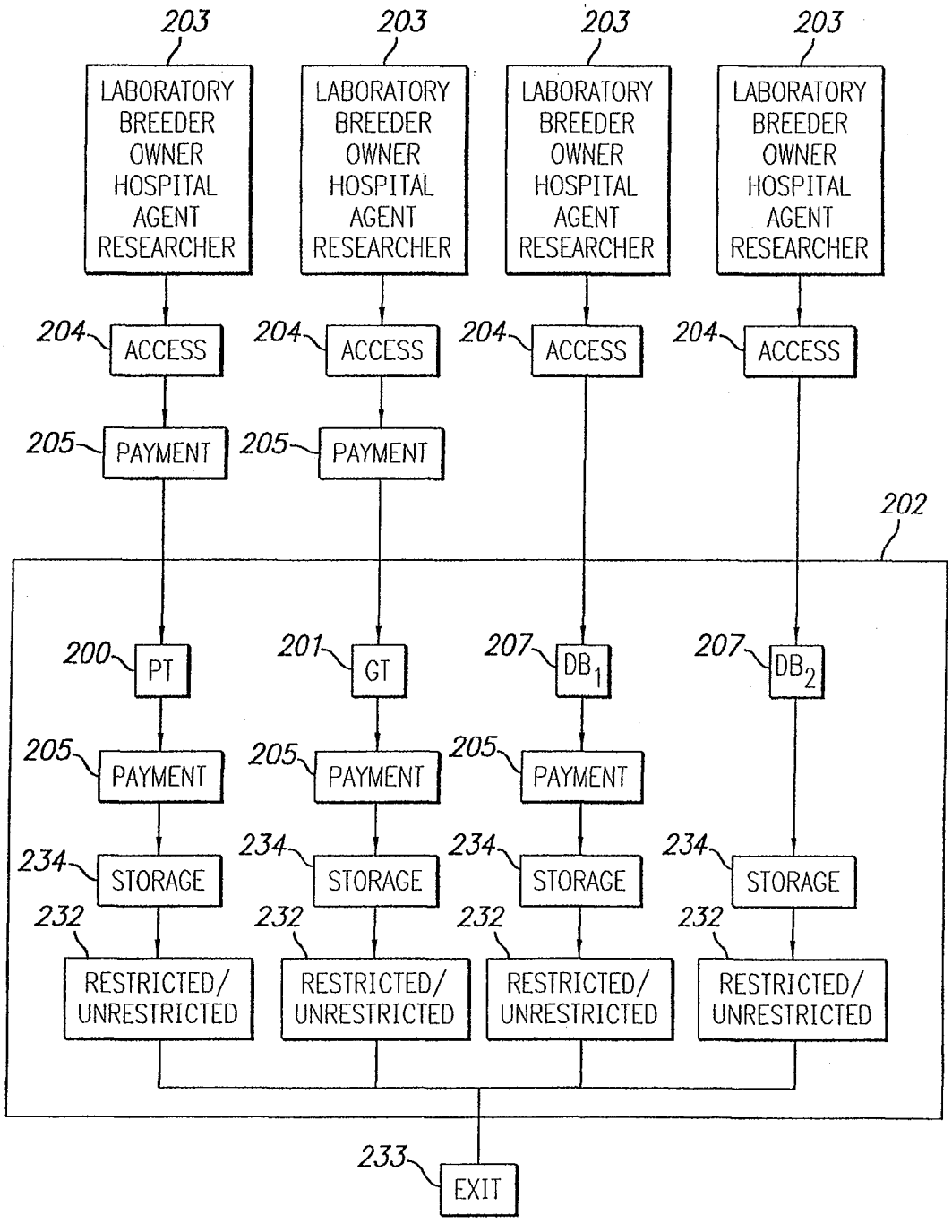
231

FIG. 6

FIG. 7


203
LABORATORY BREEDER OWNER HOSPITAL AGENT RESEARCHER
204
ACCESS
205
PAYMENT
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200
PT
201
GT
207
DB1
DB2
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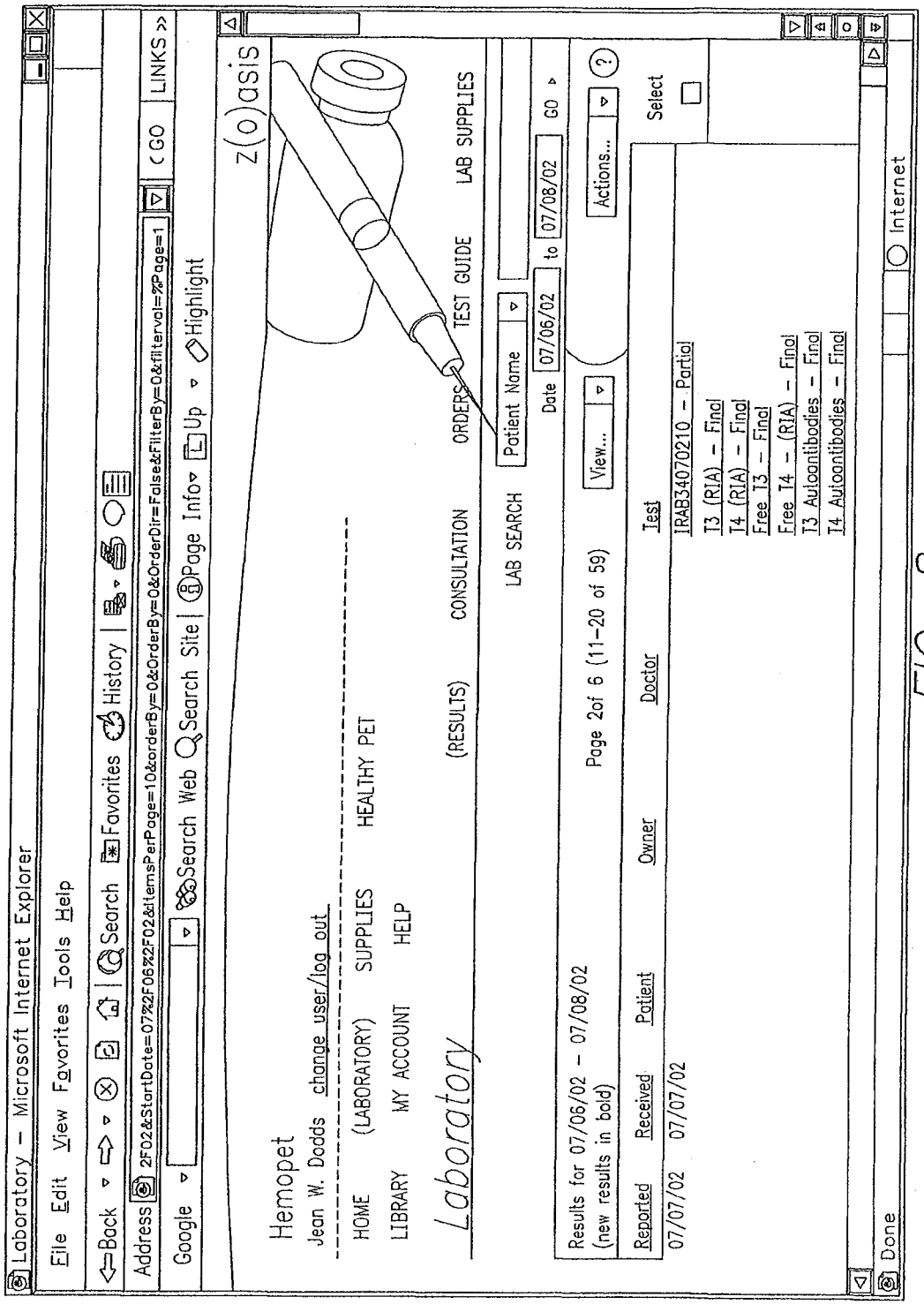
STORAGE
232
RESTRICTED/ UNRESTRICTED
233
EXIT


Laboratory – Microsoft Internet Explorer
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Back Search Favorites History
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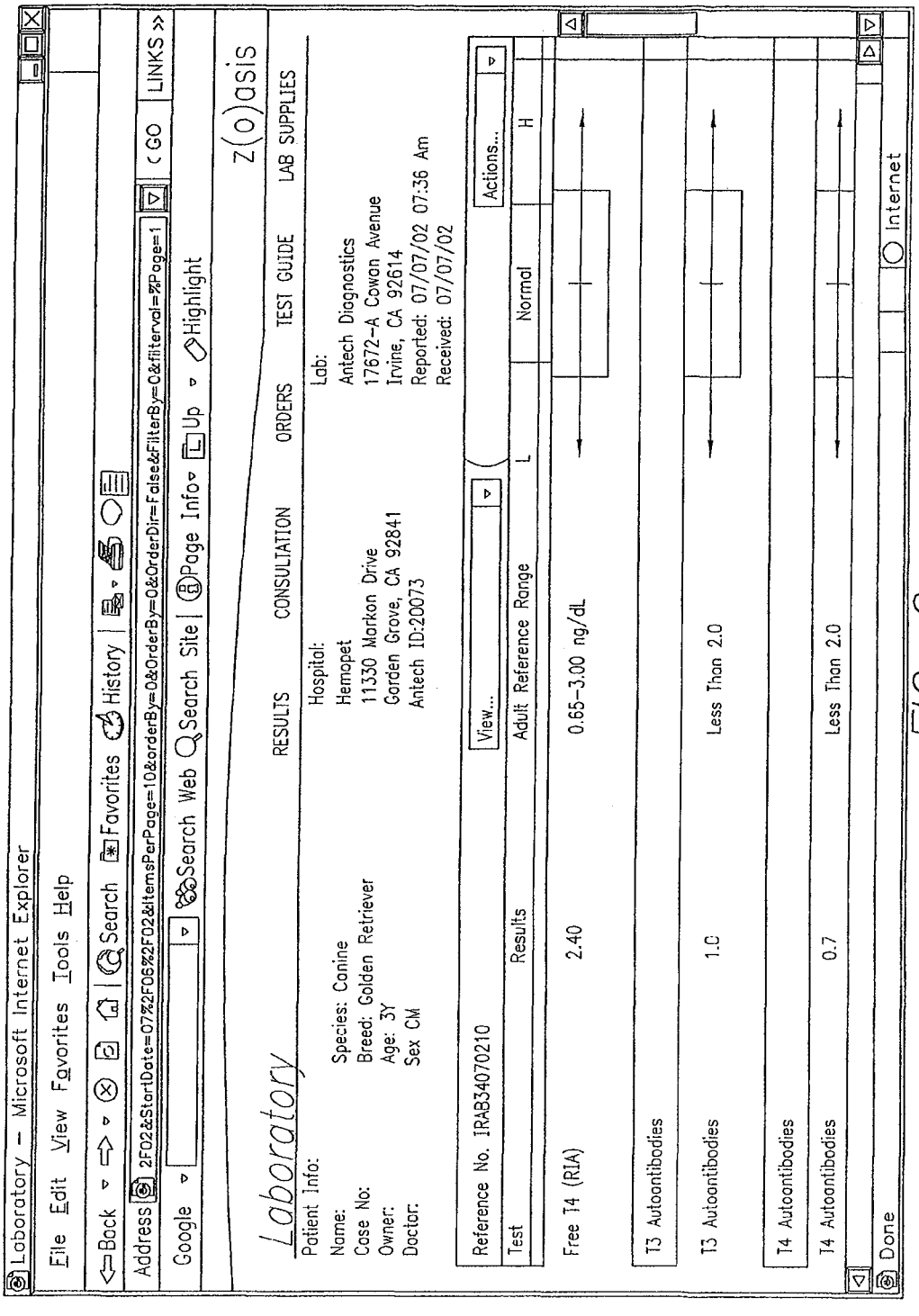
GO LINKS
Google Search Web Search Site Page Info Up Highlight
z(o)asis
Hemopet
Jean W. Dodds change user/log out
HOME (LABORATORY) SUPPLIES HEALTHY PET
LIBRARY MY ACCOUNT HELP
Laboratory
(RESULTS) CONSULTATION ORDERS TEST GUIDE LAB SUPPLIES
LAB SEARCH
Patient Name
Date 07/06/02 to 07/08/02 GO
Results for 07/06/02 - 07/08/02
(new results in bold)
Page 2of 6 (11-20 of 59)
View... Actions...
Reported Received Patient Owner Doctor Test Select
07/07/02 07/07/02
IRAB34070210 – Partial
T3 (RIA) – Final
T4 (RIA) – Final
Free T3 – Final
Free T4 – (RIA) – Final
T3 Autoantibodies – Final
T4 Autoantibodies – Final
Done
Internet

FIG. 8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Back Search Favorites History
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Google Search Web Search Site Page Info Up Highlight
GO LINKS
z(o)asis
Laboratory
RESULTS CONSULTATION ORDERS TEST GUIDE LAB SUPPLIES
Patient Info:
Name:
Case No:
Owner:
Doctor:
Species: Canine
Breed: Golden Retriever
Age: 3Y
Sex CM
Hospital:
Hemopet
11330 Markon Drive
Garden Grove, CA 92841
Antech ID:20073
Lab:
Antech Diagnostics
17672-A Cowan Avenue
Irvine, CA 92614
Reported: 07/07/02 07:36 Am
Received: 07/07/02
Reference No. IRAB34070210
View...
Actions...
Test
Results
Adult Reference Range
L
Normal
H
Free T4 (RIA)
2.40
0.65-3.00 ng/dL
T3 Autoantibodies
T3 Autoantibodies
1.0
Less Than 2.0
T4 Autoantibodies
T4 Autoantibodies
0.7
Less Than 2.0
Done
Internet

FIG. 9

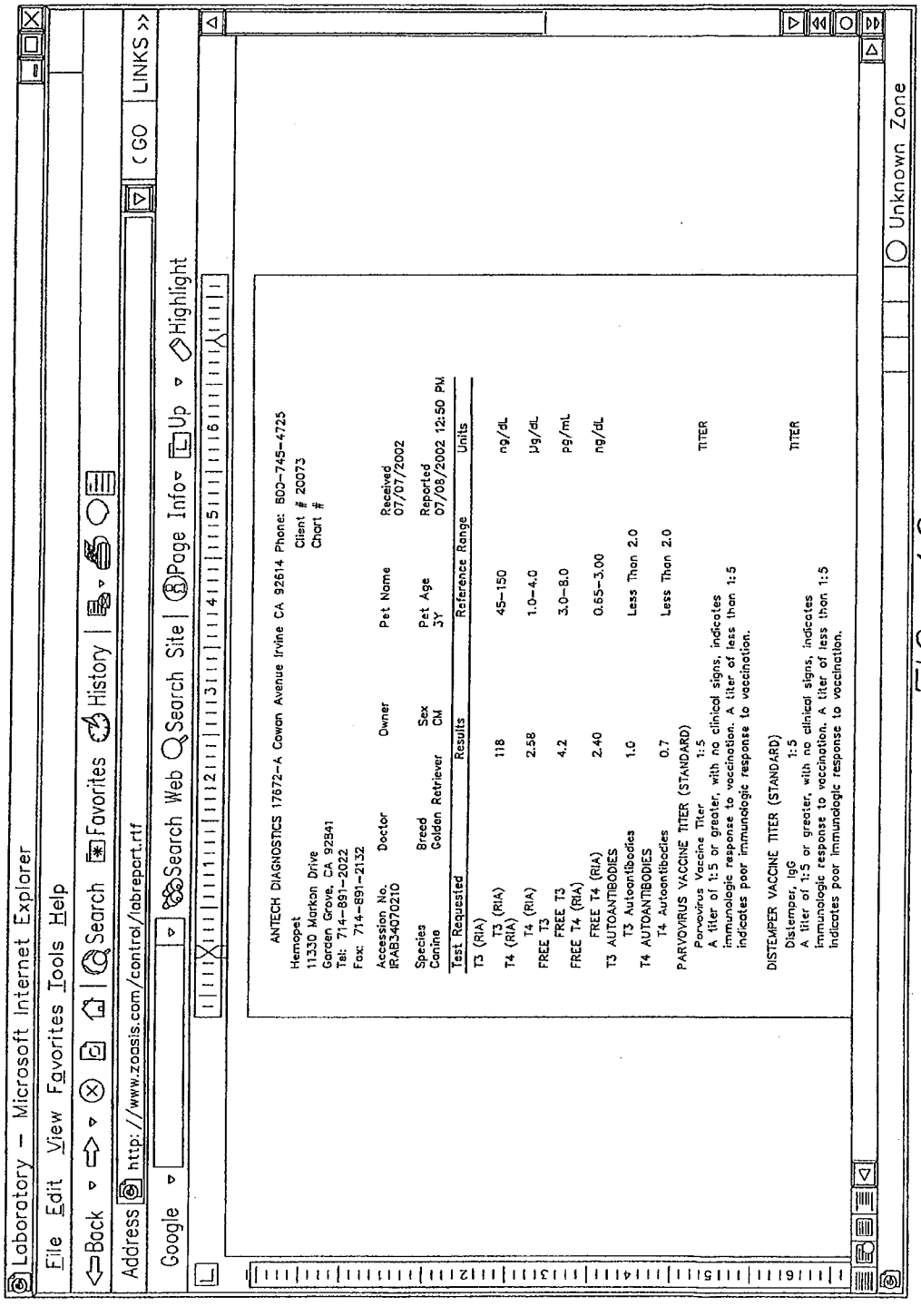
Laboratory - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites History
Address http://www.zoasis.com/control/labreport.rtf
Google
Search Web Search Site Page Info Up Highlight
GO LINKS
Unknown Zone
ANTECH DIAGNOSTICS 17672-A Cowan Avenue Irvine CA 92614 Phone: 800-745-4725
Hemopet
11330 Markon Drive
Garden Grove, CA 92841
Tel: 714-891-2022
Fax: 714-891-2132
Client # 20073
Chart #
Accession No. IRAB34070210
Doctor
Owner
Pet Name
Pet Age 3Y
Received 07/07/2002
Reported 07/08/2002 12:50 PM
Species Canine
Breed Golden Retriever
Sex CM
Test Requested
Results
Reference Range
Units
T3 (RIA)
T3 (RIA) 118 45-150 ng/dL
T4 (RIA) 2.58 1.0-4.0 µg/dL
FREE T3 4.2 3.0-8.0 pg/mL
FREE T4 (RIA) 2.40 0.65-3.00 ng/dL
T3 AUTOANTIBODIES 1.0 Less Than 2.0
T4 AUTOANTIBODIES 0.7 Less Than 2.0
PARVOVIRUS VACCINE TITER (STANDARD) TITER
Parvovirus Vaccine Titer 1:5
A titer of 1:5 or greater, with no clinical signs, indicates immunologic response to vaccination. A titer of less than 1:5 indicates poor immunologic response to vaccination.
DISTEMPER VACCINE TITER (STANDARD) TITER
Distemper, IgG 1:5
A titer of 1:5 or greater, with no clinical signs, indicates immunologic response to vaccination. A titer of less than 1:5 indicates poor immunologic response to vaccination.

FIG. 10

ANTECH DIAGNOSTICS 17672-A Cowan Avenue Irvine CA 92614 Phone: 800-745-4725

Hemopet
11330 Markon Drive
Garden Grove, CA 92841
Tel: 714-891-2022
Fax: 714-891-2123

Client # 20073
Chart #

Accession No.	Doctor	Owner	Pet Name	Received
IRAB34070210	CASE	**BERKSHIRE**	GIPPER	07/07/2002

Species	Breed	Sex	Pet Age	Reported
Canine	Golden Retriever	CM	3Y	07/08/2002 12:50 PM

Test Requested	Results	Reference Range	Units
T3 (RIA)			
T3 (RIA)	118	45-150	ng/dL
T4 (RIA)			
T4 (RIA)	2.58	1.0-4.0	µg/dL
FREE T3			
Free T3	4.2	3.0-8.0	pg/mL
FREE T4 (RIA)			
Free T4 (RIA)	2.40	0.65-3.00	ng/dL
T3 AUTOANTIBODIES			
T3 Autoantibodies	1.0	Less Than 2.0	
T4 AUTOANTIBODIES			
T4 Autoantibodies	0.7	Less Than 2.0	
PARVOVIRUS VACCINE TITER (STANDARD)			
Parvovirus Vaccine Titer	1:5		TITER
A titer of 1:5 or greater, with no clinical signs, indicates immunologic response to vaccination. A titer of less than 1:5 indicates poor immunologic response to vaccination.			
DISTEMPER VACCINE TITER (STANDARD)			
Distemper, IgG	1:5		TITER
A titer of 1:5 or greater, with no clinical signs, indicates immunologic response to vaccination. A titer of less than 1:5 indicates poor immunologic response to vaccination.			

THYROGLOBULIN AUTOANTIBODIES (Pending)

FIG. 11

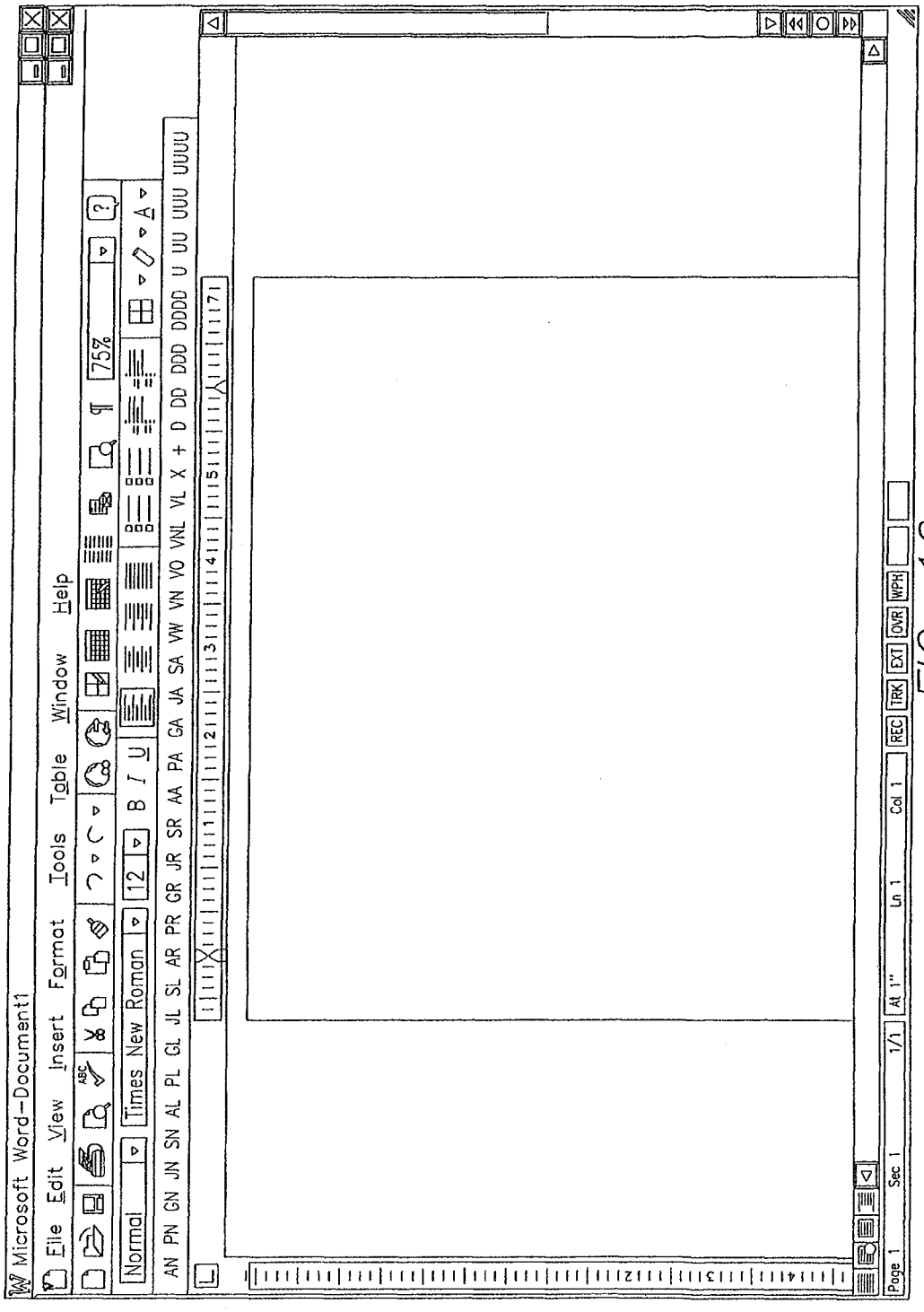
Microsoft Word - Document1
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FIG. 12

tstsub.htm

(R) 10F3

TEST REQUEST SUBMISSION FORM

W. Jean Dodds, DVM

HEMOPET 11330 Markon Drive, Garden Grove, CA 92841 *Please Note: New Address & Phone Number*

PHONE: 714/ 891-2022 *FAX: 714/ 891-2123*

(DR. DODDS/HEMOPET: ANTECH ACCT. #20073)

QNS for Rabies

Date: _____

Veterinarian/ Clinic: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

Client: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

ANIMAL INFORMATION: Canine Cold Ref Feline _____ Equine _____ Other _____

Pet Name: _____ Breed: _____ F ___ M ✓ Altered: Yes ✓ No ___

Date of Birth: 12/28/98 Weight: 78

Brief History & Reason For Test: MAY 9/10 INFLAMMATORY THYROIDITIS IRAB32024700 5/4/02

(Check test or tests desired and enclose appropriate fees)

Tests:	Cost:
___ Thyroid Antibody Profile (D8T) Profile (If on therapy, what dose and how many hours post-pill?)	$ 37.50
___ -- ADD ON TSH to D8T	$ 19.00
___ -- ADD ON TgAA to D8T	$ 17.00
___ von Willebrand Test (vWD)	$ 33.00
___ Profile 6400 (Thyroid & vWD)	$ 56.50
___ Profile 7200 (CBC, Differential, Superchem & Thyroid Antibody Profile)	$ 59.50
___ Profile SA150 (7122) Distemper & Parvo Vaccine Titers	$ 28.00

✓ Thyrozine .7mg bid.
LAST PILL 4:35AM 7-5-02
CHECK SENT BY OWNER:
PAID 7/6/02
CHECK # 7894
AMOUNT $160.00

http://www.itsfortheanimals.com/TSTSUB.HTM

FIG. 13

ANTECH DIAGNOSTICS 17672-A Cowan Avenue Irvine CA 92614 Phone: 800-745-4725

Hemopet
11330 Markon Drive
Garden Grove, CA 92841
Tel: 714-891-2022
Fax: 714-891-2123

Retest
IRAB32024700
5/4/02

Client # 20073
Chart #

5 hrs post-pill Thyrozine 0.7mg BID

Accession No.	Doctor	Owner	Pet Name	Received
IRAB34070210	CASE	BERKSHIRE	GIPPER	07/07/2002
Species	Breed	Sex	Pet Age	Reported
Canine	Golden Retriever 78 lbs	CM	3YRS 7 MO	07/08/2002 12:50 PM

Test Requested		Results	Reference Range	Units
T3 (RIA)				
T3 (RIA)		118	45-150	ng/dL
T4 (RIA)				
T4 (RIA)	↓	2.58	1.0-4.0	µg/dL
FREE T3				
Free T3		4.2	3.0-8.0	pg/mL
FREE T4 (RIA)				
Free T4 (RIA)		2.40	0.65-3.00	ng/dL
T3 AUTOANTIBODIES				
T3 Autoantibodies		1.0	Less Than 2.0	
T4 AUTOANTIBODIES				
T4 Autoantibodies		0.7	Less Than 2.0	
PARVOVIRUS VACCINE TITER (STANDARD)				
Parvovirus Vaccine Titer		1:5 ADEQUATE LEVEL		TITER
A titer of 1:5 or greater, with no clinical signs, indicates immunologic response to vaccination. A titer of less than 1:5 indicates poor immunologic response to vaccination.				
DISTEMPER VACCINE TITER (STANDARD)				
Distemper, IgG		1:5		TITER
A titer of 1:5 or greater, with no clinical signs, indicates immunologic response to vaccination. A titer of less than 1:5 indicates poor immunologic response to vaccination.				
→ **THYROGLOBULIN AUTOANTIBODIES (Pending)**				

7/8/02
Dear Colleague: T4 looks low here but rest is adequate.

Adult Optimal Levels T4 3-5 µg/dl FT4 1-3 ng/dl T4AA < 2.0
T3 50-150 ng/dl FT3 3-8 pg/ml T3AA < 2.0

2

X Optimal therapeutic response levels should be in the upper 1/3 to 25% above the upper limits of the resting optimal ranges at 4-6 hours post-BID thyroid medication.

X Thyroid levels are fine at the current dose. Recommend annual retesting. unless T3AA remains as high as 5/4/02 (>4000!)

☐ Thyroid levels are too high. Recommend reducing current dosage of thyroid supplement by ____ (e.g. _____ mg BID), and retest after another 4-6 weeks.

FIG. 14A

Accession No.	Doctor	Owner	Pet Name
IRAB34070210	CASE	BERKSHIRE	GIPPER

Test Requested	Results	Reference Range	Units

☐ Thyroid levels are too low. Recommend increasing current dosage of thyroid supplement by _____ (e.g. _____ mg BID), and retest after another 4-6 weeks.

M.J. Lean Brooks, DVM

Vaccine Titer Serology

X Serologic/vaccine titers for distemper and parvovirus show adequate humoral immunity indicating that this dog should respond with a boosted anamnestic response to afford protection against these agents upon exposure.

X Recheck serologic/vaccine titers annually.

M.J. Lean Brooks, DVM

FIG. 14B

Adult Optimal Levels	T4 2-4 μg/dl T3 50-150 ng/dl	FT4 1-3 ng/dl FT3 3-8 pg/ml	T4AA < 2.0 T3AA < 2.0

- ☐ Thyroid levels are adequate, borderline normal, very good, or excellent.
- ☐ Recommend annual retesting during anestrus.
- ☐ Thyroid results are borderline normal. Recommend retesting in _____ months.

W. Jean Dodds, DVM

Adult Optimal Levels	T4 2-4 μg/dl T3 50-150 ng/dl	FT4 1-3 ng/dl FT3 3-8 pg/ml	T4AA < 2.0 T3AA < 2.0

- ☐ Thyroid levels are below minimal expectations for a healthy performance adult (at least 1.5 μg/dl for T4 and 1.0 ng/dl for FT4).
- ☐ Thyroid levels are too low. Recommend 6-8 weeks of Soloxine® or equivalent product at 0.1mg per _____lbs twice daily (e.g.____mg BID) is recommended, followed by retesting thyroid profile 4-6 hours post-pill to monitor response levels.
- ☐ If clinical signs support thyroid dysfunction, a 6-8 week trial of Soloxine® or equivalent product at 0.1mg per _____ lbs twice daily (e.g. _____ mg BID) is recommended, followed by retesting thyroid profile 4-6 hours post-pill to monitor response levels.
- ☐ Optimal therapeutic response levels should be in the upper 1/3 to 25% above the upper limits of the resting optimal ranges at 4-6 hours post-BID thyroid medication.

W. Jean Dodds, DVM

Adult Optimal Levels	T4 2-4 μg/dl T3 50-150 ng/dl	FT4 1-3 ng/dl FT3 3-8 pg/ml	T4AA < 2.0 T3AA < 2.0

- ☐ These results confirm autoimmune thyroiditis, the heritable form of canine thyroid disease. Elevated levels of T3AA and/or T4AA cause spurious elevations in T3/FT3 and/or T4/FT4 because these circulating autoantibodies interfere with laboratory tests of thyroid analytes. The lymphocytic infiltration and gradual destruction of thyroid tissue progresses to end-stage hypothyroidism, as determined by the clinical signs and low T4 and/or FT4 values referable to

FIG. 15A

thyroid disease. Recommend 6-12 weeks of Soloxine ® or equivalent product at 0.1 mg per _____lbs twice daily (e.g. _____ mg BID). Retest thyroid profile drawing the sample 4-6 hours post-pill (to reassess levels which should be upper 1/3 to 25% above the resting ranges, and see if thyroid AA levels are waning).

☐ Elevated levels of thyroglobulin autoantibodies are diagnostic of lymphocytic thyroiditis.

☐ As autoimmune thyroiditis is the heritable form of canine thyroid disease, we do NOT recommend using this dog for breeding.

W. Jean Dodds, DVM

Von Willebrand Disease

☐ vWF: Ag level is normal.

☐ vWF: Ag level is probably normal. You may elect to retest this dog at some later date to confirm status.

☐ vWF:Ag level is borderline normal (equivocal) indicating that the dog may be a carrier of von Willebrand disease (vWD). What do we know about the vWD status of the parents? Recommend retesting or breeding this dog only to mates with normal vWF:Ag levels (>70%), and checking their pups.

☐ vWF:Ag level is abnormal indicating that the dog is a carrier of vWD. What do we know about the vWD status of the parents? Recommend breeding only to mates with normal vWF:Ag levels of (>70%), and checking their pups.

☐ vWF:Ag level is low and this patient has clinical signs of a bleeding tendency, indicating presence of vWD (affected animal). We do not recommend using the animal for breeding. Please contact us if we can help with advice and/or blood products to treat the dog (HEMOPET blood bank # 949-252-8455).

W. Jean Dodds, DVM

Vaccine Titer Serology

☐ Serologic/vaccine titers for distemper and parvovirus show adequate humoral immunity indicating that this dog should respond with a boosted anamnestic response to afford protection against these agents upon exposure.

☐ Recheck serologic/vaccine titers annually.

FIG. 15B

- ☐ Serologic/vaccine titers show humoral immunity for distemper and parvovirus of less than optimal levels. This may mean that the dog is less than adequately protected against these agents in the event of exposure.
- ☐ Recommend booster vaccination for distemper and parvovirus. Recheck titers again after at least 3 weeks or assume that humoral immunity has been boosted appropriately.
- ☐ Consider booster vaccination for distemper and parvovirus unless the dog has history of adverse vaccine reaction, immune-mediated disease, or some other immune dysfunction.
- ☐ Minimize risk for exposure to infectious diseases by avoiding areas where many animal congregate or exercise etc.

W. Jean Dodds, DVM

FIG. 15C

METHOD OF ANALYZING NUTRITION FOR A CANINE OR FELINE ANIMAL

RELATED APPLICATION

This application is a divisional of application Ser. No. 10/635,707, filed Aug. 5, 2003, now issued U.S. Pat. No. 7,548,839, which is a continuation-in-part of and relates to application Ser. No. 09/419,192, filed Oct. 15, 1999, now issued U.S. Pat. No. 6,730,023, and also application Ser. No. 09/432,851 filed Nov. 2, 1999 now issued U.S. Pat. No. 6,287,254. This Application also relates to Provisional Application No. 60/403,203, filed Aug. 12, 2002. The contents of all those applications are incorporated by reference herein.

BACKGROUND

1. Field

This disclosure is concerned with animal health diagnosis. More particularly, the disclosure is directed to the testing, diagnosis and prediction of diseases and disorders of animal companions, for instance dogs and cats.

Further this disclosure relates to a method, system and apparatus for the management of comprehensive and cumulative genetic and health assessment databases in relation to animals worldwide. In particular, the disclosure relates to a bioinformatics system and its implementation in relation to animal biological data.

More specifically the disclosure is directed to animal health care, well-being and nutrition, and methods and systems for enhanced determination of these factors.

2. General Background

There is a need for a new database management bioinformatics scheme and relational database, together with computerized networks that manage, analyze, and/or integrate comprehensive and cumulative animal health assessment data and genetic identifier, genomic mapping, and genetic assessment data. A comprehensive approach to animal health and genetic selection or management of animals, and their clinical care is the subject of the present disclosure.

Current laboratory and research systems and computerization have not achieved this, nor have communication protocols been used effectively in this technological area to facilitate such a relationship or relational bioinformatics database system for management and dissemination of this comprehensive and cumulative information.

More specifically, it is necessary in animal health diagnosis and care that appropriate predictive testing for diseases and disorders of animals be achieved in order to reduce morbidity and mortality, and improve the quality of life and lifespan. Currently this is not done in relation to the health assessment data of an animal together with the genetic data related to that same animal. Current tests do not provide as much data as possible to attain correct diagnosis and disorder predictions with the net result of an improvement in the quality of life and increased longevity.

More so, currently available testing is unnecessarily complex and expensive in relation to the ability to be an accurate predictor of diseases and disorders in animals, and hence their likely longevity.

Additionally there is a difficulty of easily obtaining, reading, diagnosing and reporting to clients the diagnosis in a fast and effective means. Many systems are too complicated and have been premised on the basis of total automation. There is a need for permitting the effective human interaction in computerized data for achieving effective diagnosis, and reporting of that diagnosis in a user-friendly manner.

SUMMARY

The disclosure is directed to a method, apparatus and system of obtaining, analyzing and reporting laboratory test data in relation to the health assessment data of an animal together with the genetic data related to that same animal.

The disclosure also provides a bioinformatics system for inputting, controlling, analyzing and outputting of a broad range of criteria related to the health, genetic background and longevity of animals. This includes a system concerning phenotype data and genetic data relating to animals. Further, there is provided a system for screening of genetic data and genomic mapping, and integrating the phenotype health assessment data and genetic identifier and assessment data in a computerized data processing resource ("CDPR"). Moreover, there is provided a system for analyzing the health assessment or phenotypic data with the interrelated genetic or genotypic data. Thereafter, those data and analyses are communicated from the CDPR in a broad range and in a manner that has not previously been possible.

The present disclosure offers a unique solution to above-described problems by providing an apparatus, method and system, in relation to animals, for performing data analyses of biological specimens from specific subject animals or animal groups in relation to specific subject animal or animal groups of genetic data. The apparatus, method and system comprises a controller for obtaining, inputting, and analyzing biological, physiological, and pathological test data together with genomic mapping and genetic screening data into the CDPR.

The biological, physiological, and pathological data of the subject animal or animal group and the genetic data of the subject animal or animal group are communicated to a remote user as raw data or as related, analyzed biological, physiological, and pathological data and genetic data. The remote user can also appropriately access the CDPR to input data to, or obtain data from, the CDPR.

According to a further aspect of the disclosure there is a dynamic method and system of managing the health care and well-being of a non-livestock pet animal subject.

A computer is at least one of an expert system or interrelationship program or network for determining data base and data relationships. This can be a system such as a neural network, or other statistical sampling systems and networks.

The disclosure also includes the step of reporting the determination of the health care, well-being, nutrition or other therapeutic requirements and suggestions or health on a communications network including the Internet. Preferably, there is a payment procedure for the report which is achieved through the Internet. This communication network and structure is described here in further detail.

There is provided means for inputting data into databases, storing the data in these databases, analyzing the data in a relational sense from the different databases, and retrieving the data from these databases, namely the databases which are part of the CDPR.

A further aspect of the disclosure is the accessibility of the health assessment database and/or genetic database or other databases of the CDPR by the remote user selected on the basis of password, security control, and financial payment such that the data can be transmitted into and from the CDPR by a computer network. Use of selected passwords, encryption systems, and payment systems are employed to facilitate and restrict the flow of data in and/or out of the databases.

Alerts can be set up to advise of attempts at unauthorized access to the CDPR. The computer network may conveniently include the Internet.

As required, the data in the CDPR can also be distributed to multiple authorized remote parties, namely third parties for research or other analysis. The disclosure also includes a method and system for achieving this.

A diagnosis of the health of an animal is obtained through a combination of computerized data analysis, and human interpretation. Data relates to the physical characteristics of the animal, and includes data obtained from a physical inspection of the animal. A blood or other fluid sample is used to obtain a computer generated laboratory analysis. This is reported through an internet network to specialist for analysis by a specialist clinical pathologist. The clinical pathologist has the data relating to the physical characteristics, and thereby makes a diagnosis of the animal 's overall health status.

A drop-down menu on a computer screen provides supplemental reports to support the diagnosis. This supplemental report can be generated electronically as determined by criteria pre-selected by a specialist which matches the analysis and the data relating to the physical characteristics

This can be enhanced by further input from the specialist pathologist through an entry, selectively a keyboard entry, into the computer to obtain an integrated computer report having the laboratory analysis, supplemental report, and selectively, an enhanced report. Oral input to a computer through voice recognition software may be effective in developing the enhanced report. The integrated or enhanced report is electronically or otherwise communicated to a remotely located client.

In one preferred form of the disclosure, the laboratory analytical report is reported in a first computer program and the drop down-menu is in a second computer program. The data from the first computer program is transferred to the second computer program.

The electronic communication to the client is selectively by e-mail or fax, and the second computer program includes a utility to transmit the integrated report from the second program through the utility.

In the system using a drop-own menu, the drop-down menu is contained in a tool bar supplementing an application, selectively a word processing program. Computer program applications other than word processing applications may be the basis for the supplemental report. The tool bar includes icons defining predetermined supplemental report characteristics, and selected icons may be used by the clinical pathologist to supplement the laboratory analytical report. The icons can be grouped for animal characteristics dependant on age and sex. Alternatively or additionally, the icons are grouped for animal characteristics dependant upon animal grouping. Alternatively or additionally, the icons are grouped for selected disease states, examples of the states being selectively thyroid disease, behavior, autoimmune disease, and cancer. The icons also can be grouped for selected levels of immunity from infectious disease, that being the titer of immunity from the disease causing agent (s) in the animal, and therefore the need for vaccination of the animal against the disease.

The menu, represented by the icons, which define predetermined supplemental report characteristics, are selected to be used by the clinical pathologist to supplement the laboratory analytical report, whether the supplemental report is generated automatically by computer or by manual input from the specialist. The menu can be grouped for animal characteristics dependant on age and sex. Alternatively or additionally, the menu is grouped for animal characteristics

dependant on animal grouping. Alternatively or additionally, the menu is grouped for selected disease states, examples of the states being selectively thyroid disease, behavior, autoimmune disease, and cancer. The menu also can be grouped for selected levels of immunity from infectious disease, that being the titer of immunity from the disease agent(s) in the animal, and therefore the need for vaccination of the animal against the disease.

The data includes a panel of tests related to at least one of endocrine function, immunologic function, gastrointestinal function and nutritional analysis, inborn errors of metabolism, paternity, DNA fingerprinting, hemostasis and coagulation function, vaccinal antibody status, adverse and potential adverse vaccine reaction, infectious diseases, pathology, blood typing and bone marrow analysis, cell cytotoxicity, cytokine and allergy testing, and markers of neoplastic and paraneoplastic change. These data are relevant to the likely morbidity, likely longevity, and/or the potential risk for disease or disorder for the animal.

A method and system of obtaining and electronically delivering an assessment of the thyroid function of an animal is achieved through a combination of computerized data and human interpretation related to the animal. Data relating to the physical characteristics of the animal is obtained, the data being from at least one of a physical inspection of the animal, family and breed history, and the data submitted to a clinical pathologist. A blood or other body fluid sample from the animal is submitted for laboratory analysis of the total T4, total T3, free T4, free T3, T3 autoantibody, T4 autoantibody and thyroglobulin autoantibody. Endogenous TSH also can be measured.

A computer generated report of the laboratory analysis is obtained, and reported through a network, selectively an internet network, to a clinical pathologist. The clinical pathologist has the data relating to the physical, and family and breed history characteristics, and makes a first assessment off the thyroid function of the animal. From a drop-down menu on a computer screen a supplemental report to support the assessment is generated. This can be selectively enhanced by a further input from the pathologist through data, through entry, selectively keyboard entry, into the computer. The assessment is dependant on animal grouping and/or on animal age and sex.

An integrated computer report having the laboratory analysis, supplemental report, and an selectively enhanced report is communicated to a remotely located client, such communicating being electronic.

According to a further aspect of the disclosure, data includes characteristics related to autoimmune thyroiditis of the animal. Biological laboratory test data from a bodily fluid or tissue of an animal are analyzed. The test data relate to a physiologic or genetic marker for autoimmune thyroiditis of the animal. The data relates to at least one of the results of a comprehensive thyroid autoantibody test profile, DNA fingerprint (the gene map), and markers for immunoglobulin receptors on B-cells, T-cell receptors, and protein products of the major histocompatibility complex (MHC) genes (Class I and II allellic HLA, DLA or equivalent antigenic specificities) of the animal. Example assays to screen for MHC genes include restriction fragment length polymorphism (RFLP), polymerase chain reaction (PCR) RFLP, PCR sequence-specific oligonucleotides (SSO) and PCR sequence-specific primers (SSP). The values should fall within predetermined levels as a determinant of autoimmune thyroiditis.

According to a further aspect of the disclosure, the data includes characteristics related to the tissue environment of the eye and brain (ocular and blood-brain barrier) which are